Dentistry has a Homepage

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UDENT, INC.
P.O. Box 58
Chino Hills, CA 91709
Phone: (909) 623-0409
Fax: (909) 623-9915
Email: info@udent.com

K020009

Chapter 8 - 510(k) Summary

Submitter:

UDENT, Inc.
676 Fairplex Drive
Pomona, CA 91768
Phone: 909-623-0409
Fax: 909-623-9915
Contact: Manar M. Jamal, DDS
Email: manar@udent.com

Date of Submission: December 28, 2001

Device Name:

Trade name:	Brace Eze
Common name:	Orthodontic brace irritation relief
Classification name:	Orthodontic: Appliance & Accessories (per 21 CFR section 880.6250)

Description of Device:
Brace Eze is an orally applied gel that is applied to the brackets of orthodontic braces.

The Intended Use of Device:
The intended use of Brace Eze is as a setting gel, which provides relief of the discomfort and irritation caused by orthodontic braces to the inside of the cheek and lips.

Device for Which Substantial Equivalence is Claimed:
Ortho Wax

Substantial Equivalence:
Brace Eze is substantial equivalent to other legally marketed devices in the United States. Brace Eze functions in a manner similar to and is intended for the same use as Ortho Wax cleared for marketing for Heraeus Kulzer, Inc (K924024).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Manar M. Jamal
President
UDENT, Incorpoated
676 Fairplex Drive
Pomona, California 91768

Re: K020009
Trade/Device Name: Brace Eze
Regulation Number: 872.6890
Regulation Name: Intraoral Dental Wax
Regulatory Class: I
Product Code: EGD
Dated: December 28, 2001
Received: January 02, 2002

Dear Dr. Jamal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 15 – Indications For Use

510(k) Number: K020009

Device Name: Brace Eze

Indications For Use:

Brace Ezé is intended to provide relief from the discomfort and irritation to the inside of the cheek and lips caused by orthodontic brace.

Over-the-Counter Use

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020009